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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,425	02/19/2002	Harold G. Brown	2059-0103P	1812

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EXAMINER	
UNDERDAHL, THANE E	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
10/06/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	09/890,425	BROWN ET AL.	
	Examiner	Art Unit	
	THANE UNDERDAHL	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *24-27,32-35,52,97-111 and 116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-94, 112, 113, 114, 115 and 117-132* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/27/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 7,11,12,14,19,22-27,32-37,41,42,46-48,51,52,54,59,66,69,70,72-94 and 97-132.

Detailed Action

This Office Action is in response to the Applicant's reply received 7/27/09. Claims 7, 11, 12, 14, 19, 22-27, 32-37, 41, 42, 46-48, 51-52, 54, 59, 66, 69, 70, 72-94, 97-132 are pending. Claims 24-27, 32-35, 52, 97-111, 116, are withdrawn. Claims 8-10, 13, 15-18, 20-21, 28-31, 38-40, 43-45, 49, 50, 53, 55-58, 60-65, 67-68, 71, 95, 96, are cancelled. Claims 19, 22, 23, 41, 42, have been amended. Claims 131 and 132 are new. Claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-94, 112, 113, 114, 115 and 117-132 are considered in this Office Action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/27/09 has been entered.

Response to Applicant's Arguments— 35 U.S.C § 103

The Applicant argues that the concentrations of the glycosaminoglycan such as **hyaluronic acid** (**HA**) are not taught by Della Valle et al. or Balazs and it would not be obvious to modify these concentrations since this would destroy the teachings of the prior art cited. The Applicant lists examples in Della Valle et al. that assert one of ordinary skill in the art would not have contemplated using such small concentrations of HA of 0.01% and 5.0% wt/vol as not limited in the independent claims. However, Della Valle et al. teach a very wide range of concentrations for their solutions from 0.01% to 75% (col 9, lines 4-5) that overlaps with the range claimed by the Applicant and is therefore obvious (see MPEP 2144.05, I). This contradicts Applicant's assertion that Della Valle et al. teach away from using such small concentrations. While it is true that the prior art as a whole must suggest the claimed invention, the desirability of a particular combination need not be supported by a finding that the prior art suggest that

the combination claimed is the preferred, or most desirable combination (M.P.E.P. § 2143.01). The prior art's mere disclosure of more than one alternative does not constitute a teaching away from the claimed invention because such disclosure does not criticize, discredit, or other wise discourage the solution claimed in the patent application. See In re Fulton, 391 F.3d 1195, 73 USPQ2d 1411 (2004). Indeed Della Valle et al. does not discredit using small concentrations, on the contrary, teaches that they are in such a feasible range. The rejection may be withdrawn if unexpected results for this claimed range are observed.

The Applicant argues that it would not be obvious to substitute the pure HA of Balazs into the teachings of Della Valle et al. However both patents share similar utilities for their HA compositions in that they both administer topically and to animal eyes (Della Valle, col 1, lines 54-65, Example 30; Balazs, see Abstract), specifically as mentioned in the previous office action, Balazs teaches using a low concentration of 1% HA (which is in the range limited in claim 93 as well as cancelled claim 53) solution to be administered to animal eyes such as the Owl Monkey (Balazs, see Abstract). Also Balazs and Della Valle et al. both desire their HA to be anti-inflammatory (Della Valle, col 6, lines 33-50: Balazs col 1, lines 10-25). The Examiner points out again that Della Valle et al. cite Balazs multiple times when considering the HA to use (Della Valle, col 5 and 6). Indeed Della Valle even cites Balazs as an example on purification and isolation of HA (Della Valle, col 6, lines 10-15). Therefore one of ordinary skill in the art has ample teachings as well as motivation to use the HA of Balazs in the invention of Della Valle.

The limitation that the “at least one glycosaminoglycan is the sole active ingredient” is indefinite. As mentioned previously "Activity" of a compound or molecule is extremely broad and relative. Indeed using the broadest reasonable interpretation, common molecules such as water or oxygen have some activity since both are required for normal cellular function. So the question would be what is the sole activity of the HA, or what are the activities that are excluded. The Applicant argues that in ”the context of the present invention...excludes any other active ingredient that is not a glycosaminoglycan(s)". However since this "activity" is not expressly defined in the specification to exclude other possible even inherent activities, the Examiner must follow M.P.E.P. § 2111 which guides, the pending claims must be given their broadest reasonable interpretation consistent with the specification. Broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. In *In re Prater* (citations omitted), the court ruled that “reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from reading limitations of the specification into a claim,’ to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim. The court found that applicant was advocating the latter, i.e., the impermissible importation of subject matter from the specification into the claim.

The arguments that Della Valle et al. teach that the HA is a carrier and not an active ingredient are not persuasive since as the Examiner stated previously the inherent properties of molecule cannot be ignored, including their activities just because

of how they are classified in the prior art. Furthermore arguments concerning that the teachings of Della Valle et al. exclude the use of HA as an active ingredient are similar to an intended use argument for this composition. As a composition, the invention is defined by its components and the limitations implied in the intended use are considered only if they impart a structural limitation (see M.P.E.P. § 2111.02 II). So the structure of the composition is considered in this application, such as the components, and not the intended effect or result of each component. Indeed Della Valle et al. teach the concentrations of HA that are limited in the Application and in the absence of unexpected results are obvious.

The Applicant agues that the cost of the HA provided by Balazs would preclude one of skill in the art from using it in the invention of Della Valle. However, this is argument of council as well as secondary considerations that are not supported by affidavit and while considered are prided little patentable weight (see M.P.E.P. § 2129 and § 2144.03). Indeed the Applicant does not provide any evidence of the exorbitant costs of the HA.

The Argument that the difference in purity would preclude one of ordinary skill in the art from using the HA of Balazs in the invention of Della Valle et al. are not persuasive. Both Balazs and Della Valle use their HA compositions in surgery and even apply them to the eyes (Della Valle, Example 30, col 28-29 section II, col 32 section V: Balazs, col 14, Therapeutic Uses of Purified HUA), so clearly one of ordinary skill in the art would be motivated to use the HA of Balazs et al. in their invention since they are for very similar uses.

Therefor the rejection stands and is repeated below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-94, 112, 113, 114, 115 and 117-132 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al. (U.S. Patent # 4736024) and further in view of Balazs (U.S. Patent # 4,141973).

These claims are to a composition of orally ingestible or mucosally absorbable glycosaminoglycan such as hyaluronic acid (hyaluronan or **HA**) that has at least one fraction with a molecular weight 1,000,000 daltons as measure by the protein standard/intrinsic viscosity. The composition must not contain an essential oil as an active ingredient and contains up to 5% by weight protein contaminants and a carrier selected from several forms such as a vaporizer liquid, spray, cream, ointment, drink or drink mix. The composition may also contain a second glycosaminoglycan fraction from weighing from 1,000 to less than 50,000 daltons and 100,000 to 300,000 daltons. The composition contains less than 98% HA.

Claims 54, 113 and 123 recite an intended use and a method step for their respective compositions. These intended uses do not impart a structural relationship, such as an additional component, to the composition (M.P.E.P. § 2111.02 II). Since

compositions are defined and limited by their components, these limitations are not further limiting.

Della Valle et al. teach a composition that may have fractions of HA from ~11 million to 30,000 (Della Valle, col 6, lines 1-10) for applications in human and veterinary medicine (Della Valle, col 2, lines 57-60) that is absent and essential oil as the active ingredient. This composition can be formulated into preparation for adsorption through the mucus membranes (Della Valle, col 5, lines 3-5) such as nasal sprays or oral inhalers or even gels and ointments with, pain-reliever (analgesic) anti-biotic and anti-inflammatory properties (Della Valle, col 3 and 4, entire section, specifically col 3, lines 25-35 and Examples 1-19). Since the HA can be applied orally or nasally it would have been obvious to someone skilled in the art that that HA is of at least food grade purity. Della Valle lists multiple ranges for the HA in their composition from 13 million to 30,000 as well as 50,000 to about 100,000. The amount of HA in their many compositions can vary greatly with some examples showing 34.0% and 80.0% HA (Della Valle, Example 2 and 5) or the concentrations for their solutions from 0.01% to 75% (col 9, lines 4-5).

What Della Valle et al. does not teach is that the HA is defined by its intrinsic viscosity or by the protein standard. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Balazs. He teach an ultrapure HA that can be made into a 1% optomological solution and does not cause the inflammation of owl monkey eyes (Balazs, see Abstract). His ultrapure solution of HA has a molecular weight of greater than 1,200,000 as measure

by intrinsic viscosity (Balazs, col 4, lines 40-50). The HA of Balazs also contains a protein content of less then 0.5% by weight.

It would have been obvious to someone skilled in the art to use the HA of Balazs in the compositions of Della Valle et al. A *prima facie* case can be made since Della Valle et al. directly cites this same patent in their patent (Della Valle et al., see References Cited). Also Della Valle et al. expressly mentions the work of Balazs on the isolation and use of HA in the specification of their patent (Della Valle et al., col 5, lines 15-45). Therefore one of ordinary skill in the art would be motivated and have a reasonable expectation of success to use the HA of Balazs in the invention of Della Valle et al. Also one of ordinary skill in the art would be motivated to measure their other shorter chain fractions of HA by intrinsic viscosity to make sure the have a common standard of molecular weight between the large and small fractions. Since both Balazs and Della Valle et al. teach the use of HA in the similar molecular weight range it would have been obvious to someone skilled in the art to use the HA characterized by intrinsic viscosity of Balazs in the invention of Della Valle et al since one of ordinary skill in the art would recognize these are art-defined equivalents for the same purpose and have the same predictable result. (M.P.E.P. § 2144.06 and KSR International Co. v. Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007)).

Also while neither Della Valle and Balazs teach the multiple formulations listed in claims 74-88 such as a gargle, gum, lozenge, foam or capsule they have already taught that the HA compositions are safe for oral, eye and topical application. It would have been obvious to someone skilled in the art to alter their product into these formulations

since these are simply well known variations on the formulation for oral and topical administration of compositions.

Therefore the references listed above renders obvious claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-94, 112, 113, 114, 115 and 117-132.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 132 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim includes the limitation that the "glycosaminoglycan is the sole active ingredient". This limitation is indefinite because it does not define the activity either imparted nor excluded by the glycosaminoglycan. Indeed as mentioned above the limitation "activity" is broad and can read on any physiological reaction. Indeed common thought "inert materials" such as water, oxygen, table salt (NaCl) or carbon dioxide have some inherent activity in the physiology. Therefore this new claim is indefinite. According to M.P.E.P. § 2111, the pending claims must be given their broadest reasonable interpretation consistent with the specification. Broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted

more broadly than is justified. In *In re Prater* (citations omitted), the court ruled that "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from reading limitations of the specification into a claim,' to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim. The court found that applicant was advocating the latter, i.e., the impermissible importation of subject matter from the specification into the claim.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached at (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
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/Leon B Lankford/
Primary Examiner, Art Unit 1651